Agenda Item A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 25 2003

Mr. Gregory Gonot
Deputy Attorney General
State of California
Department of Justice
1300 I Street
Sacramento, California 95814

Re: Opinion No. 03-601

Dear Mr. Gonot:

I write in response to the letter of July 28, 2003, that your colleague, Rodney O. Lilyquist, sent the United States Food and Drug Administration (FDA) regarding the importation of prescription drugs from Canada into the State of California.

I. QUESTIONS PRESENTED

Mr. Lilyquist's letter asks nine separate questions about the potential liability associated with importing prescription drugs from Canada. All nine of the questions relate to one of three basic issues:

- Questions 1 – 6 query whether it is legal to purchase drugs from Canada and import them into the State of California.

- Questions 7 – 8 query whether the federal law in this area preempts the State of California (or a county or city within the state) from enacting a law that would legalize the importation of prescription drugs from Canada.

- Question 9 queries whether public pension funds such as CALPERS or CALSTRS can negotiate for Canadian prescription drug prices for their members.

II. SHORT ANSWER

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in

Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the drug and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada, it would violate FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts the State of California (and any city or county within the state) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

III. ANALYSIS

1. Questions 1 – 6: The importation of prescription drugs from Canada

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.[1]

First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are

[1] We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited…"). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service. [2]

With respect to questions 4 and 5 of Mr. Lilyquist's letter, please note that the preceding analysis applies also in the case of sovereign Indian nations located in the State of California. FDA considers Indian Reservations to be possessions of the United States within the meaning of 21 U.S.C. § 321(a)(2). Accordingly, FDA asserts complete jurisdiction over products within the purview of the FFDCA that are imported, purchased, or sold by an Indian reservation. *See FPC v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960); *United States v.*

[2] The issue of whether persons may broker the sale of Canadian drugs through an internet operation is discussed more fully in Warning Letters that FDA sent to Rx Depot (March 21, 2003) and CanadianDiscountDrugs (June 30, 2003). A copy of those letters is enclosed and can also be obtained through FDA's website at www.fda.gov. They are particularly responsive to question number 6 in Mr. Lilyquist's letter, which queries whether an Indian nation may sell Canadian prescription drugs through a website to other residents of California.

Baker, 63 F.3d 1478, 1484 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 824 (1996); *United States v. Funmaker*, 10 F.3d 1327, 1330 (7th Cir. 1993); *EEOC v. Fond du Lac Heavy Equipment and Construction Co.*, 986 F.2d 246, 248 (8th Cir. 1993).

With respect to question 6 of Mr. Lilyquist's letter, please note also that the preceding analysis applies to persons who import drugs into the United States on their person or on a bus. In those cases where the FFDCA prohibits the importation of a prescription drug, it makes no legal difference whether that drug has been imported through the mails, delivered by a private shipping company, or carried across the border on one's person. *See* 21 U.S.C. §§ 331 and 381.

FDA's Personal Importation Policy

There has been some recent confusion in the press about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Recent advertisements in certain domestic newspapers and magazines have implied that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites have stated that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these messages is true.

The Personal Importation policy is used to help guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. *See* FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities; it does not change the law.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C.

§§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A).

Those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FFDCA, can also be found criminally liable under 18 U.S.C. §§ 2 and 371.

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad.[3] With respect to question 6 in Mr. Lilyquist's letter, please note that, as a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Please also note that, under current California law, state-sponsored importation of drugs from Canada for use in the state's Medi-Cal program may violate the statutory and regulatory requirements for this program. *See* West's Ann. Cal. Welf. & Inst. Code, § 14100, *et. seq*; Cal. Admin. Code tit. 22, § 50000, *et. seq*. For example, the importation of drugs from Canada may violate the Prudent Purchase of Drugs Program, 22 CCR § 51513.6, because the drug products are not "handled in accordance with the provisions of applicable federal and state law." In addition, we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law. FDA has not researched and does not here advise you of any tort liability that may arise under state law, but we cite the issue as a possible concern.

2. Questions 7 and 8: Federal preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Cause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

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[3] *See, e.g.*, the Warning Letter that FDA sent to Rx Depot on March 21, 2003, the Warning Letter that FDA sent to CanadianDiscountDrugs on June 30, 2003, and the letter that FDA sent the Kullman Firm of New Orleans, Louisiana on February 12, 2003. A copy of the Kullman letter has also been enclosed for your review.

The Supreme Court has held:

> under the Supremacy Clause, the enforcement of a state regulation may be pre-empted by federal law in several circumstances; first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); *see also English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "occupation of the field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). *See English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Occupying the field

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." (emphasis added) *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 US 707, 713 (1985), *quoting Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly,

Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. If the state of California were to enact a law that contravened the scheme, there is no question that the result would be inconsistent with the plain objectives of the FFDCA.

Implied conflict preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of certain drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of California to pass legislation conflicting with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

3. Question 9: Public Pension Funds

As noted above, the import prohibitions in the FFDCA apply to both public and private entities. *See* 21 U.S.C. §§ 321(e) and 331. Thus, a public pension fund would be subject to the same liability as a private citizen for a violation of the import provisions of the FFDCA.

I. Conclusion

I hope that the preceding discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many

drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that would legalize imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

Nevertheless, we are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products and generally no more expensive in the United States than the generic drugs sold elsewhere in the industrialized world. The Administration is also working with the Congress on landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely,

William K. Hubbard
Associate Commissioner for Policy and Planning

Encl: FDA letter to the Kullman Firm (February 12, 2003)
FDA Warning Letter to Rx Depot (March 21, 2003)
FDA Warning Letter to CanadianDiscountDrugs (June 20, 2003)

HEALTH

The FDA Warns Cities, States About Buying Canadian Drugs

By ANNA WILDE MATHEWS
Staff Reporter of THE WALL STREET JOURNAL

Federal regulators are moving to forestall a drive by some cash-strapped state and city governments to acquire cheaper Canadian pharmaceuticals for their employees.

The Food and Drug Administration wrote to the state of California Tuesday that state, city and county governments that import prescription drugs from Canada will nearly always be in violation of federal law. The agency also said that federal laws pre-empt state, city or county efforts to legalize the importation of drugs from Canada.

"We want to send a very strong message, which is that safety is absolutely crucial, and they need to be aware that these activities are inherently risky," said Peter J. Pitts, associate FDA commissioner for external relations.

In a separate move, the FDA is raising an alarm about a high-profile effort by the city of Springfield, Mass., to encourage its employees to register for a service that offers Canadian drugs to U.S. customers. The FDA investigated the Canadian company that is supplying Springfield's employees, dependents and retirees. Senior FDA officials said the agency plans to follow up with a warning letter to the company, CanaRx Services Inc., informing it that the FDA believes its activities run afoul of American law by sending unapproved drugs to U.S. patients.

Gloria Howard, administrator of CanaRx, said the company hasn't received a warning letter and she had "no response." The company is based in Windsor, Ontario, but maintains a post-office box as a mailing address in Michigan, she said.

Michael Albano, Springfield's mayor, said he remains confident about the safety of the products that he and other city workers are getting through CanaRx. "I'm not going to stop," he said. "It's the right thing to do for my employees and my city." He decided to encourage city employees to use the company to cut the health-care costs for the 20,000 people who participate in Springfield's plan.

The new program, which went into effect July 8, could save the city $4 million to $9 million from a projected $18 million annual pharmaceuticals bill, Mr. Albano estimated. The plan will raise employees' co-payments for U.S. drugs, while charging them nothing for the same products from Canada. The Canadian plan is meant only for drugs taken on an ongoing basis, not for urgent needs such as antibiotics.

The FDA is taking action as more state and local governments are considering such drug imports and some are asking the agency's advice. The possibility of sharply cutting employee drug costs -- Canadian drugs can be one-third to one-half the price of U.S. versions, because of price controls and a favorable exchange rate -- has sparked intense interest among government officials in the U.S.

The agency's letter to California, as well as its move in the Springfield case, might cool officials' eagerness to explore the notion.

"I don't want to do anything that's illegal," said Rolland Grant, mayor of East Providence, R.I. The city of 48,000 has put together a committee to create a Canadian-drug initiative for both its own employees and other residents. Still, Mr. Grant, who decided to look into the idea after reading about the Springfield plan, says he is confident that East Providence can find a legitimate and safe Canadian supplier.

FDA officials, including Commissioner Mark McClellan, repeatedly have raised concerns with Congress about the safety of imported drugs. Lawmakers are expected to debate the issue when Congress returns in September. Currently, it is illegal for anyone but a drug's maker to reimport U.S.-made drugs from abroad, and no drugs are supposed to be used in the U.S. that aren't made in FDA-inspected facilities. Legislation that would allow individuals to acquire drugs from other countries has gained momentum.

Previously, the FDA has tried to get tough on companies that serve as intermediaries in ferrying drug imports to U.S. consumers. In March, the FDA sent a warning letter to Rx Depot Inc., of Tulsa, Okla., stating that its business of helping U.S. citizens purchase medicines from Canada violated federal law. So far, the FDA has steered away from going after consumers who use such intermediaries.

The strongly-worded letter to California officials is the agency's response to questions from the California attorney general's office regarding such plans. The agency said that "almost every time a city, county, or state program imported a drug from Canada, that program would violate" federal law. In addition, "programs that cause illegal shipments also violate" the law.

The agency's concern about Springfield's Canadian supplier sends a message that is likely to stretch beyond the city of 152,000 people. The FDA investigated CanaRx by ordering an insulin product in a sting operation. According to the FDA, the drug, which needed to be chilled, arrived at room temperature, raising a safety issue. Ms. Howard, of CanaRx, said the company's policy is to send drugs that need to be refrigerated by next-day shipment, and keep them chilled during shipment.

Mr. Albano, the Springfield mayor, said he felt the FDA had unfairly focused on his supplier in an attempt to send a message to him and other cities. "Why are they [CanaRx] being singled out all of a sudden?" he said. The mayor plans to meet with FDA officials Sept. 16.

The FDA's Mr. Pitts said: "The mayor of Springfield brought his supplier to our attention. It would have been irresponsible of us not to have investigated."

Mr. Albano received a great deal of attention when he began publicizing his plan several months ago. In a newspaper editorial and national television interviews, he said he had visited CanaRx's facilities, and felt confident enough to use the company to order insulin and other supplies for his diabetic son.

So far, Mr. Albano said, about 700 employees have registered for the Canadian option. Despite the FDA's findings, "We've not had any incidents," he said.

Write to Anna Wilde Mathews at anna.mathews@wsj.com1

Paul Riches
09/02/2003 09:44 AM

cc:
Subject: fyi

Posted on Sun, Aug. 31, 2003

Canada's drug bust
U.S. drugmakers block discounted meds from north of border.
By Tom Cohen
Associated Press

TORONTO - In the last eight months, the outlook for Daren Jorgenson's CanadaMeds.com business has gone from upbeat to uncertain.

A strategy by major drug companies to limit supplies to Canadian Internet pharmacies is stifling the industry, driving up prices and frustrating American consumers looking for cheaper medicines north of the border.

"I still think there's quite a bit of savings, but as time goes by, as prices go up, it could really limit the growth of the industry," said Jorgenson, the chief executive officer of CanadaMeds.com.

U.S.-based Pfizer Inc., the world's largest pharmaceutical-maker, in August became the fourth drug company to act against the sale of discounted Canadian prescription drugs to Americans. Those actions followed similar moves by GlaxoSmithKline P.L.C., AstraZeneca Pharmaceuticals L.P. and Wyeth, which all have major operations in the Philadelphia area.

A letter Pfizer sent to dozens of Canadian pharmacies said it would sell its products directly only to the pharmacies instead of through wholesalers. If a Canadian pharmacist orders more than its domestic market dictates, Pfizer can cut the supply to prevent the medicine from being resold to Americans.

The squeeze on supplies has forced some Canadian operations out of business, while others are raising prices and buying stock from friends in the business to fill U.S. orders still rushing in.

"Until further notice, we are not accepting any more or-

ders," says the Web site for Can-ada Discount Pharmacy, www. canadadiscountpharmacy. com. It goes on to say the domain and associated software are for sale.

The result could be a crippled industry that so far has enjoyed a brief but profit-filled existence mailing lower-priced Canadian medicine to American customers.

"I would expect by the end of this year that the 100 pharmacies who are in it

will be down to 10 or so," predicted Dave Robertson, the founder of crossborderpharmacy.com, one of the largest Canadian operations. "Strategically [the drug companies are] doing a very good job... . They are whittling away our will to survive."

In Berkeley, Calif., 80-year-old Peggy Hammerquist said Robertson's crossborderpharmacy. com recently was unable to guarantee her three-month supply of Celexa, an antidepressant. She was down to seven pills - or one week's worth - when the pharmacy got a new shipment and filled her order.

"It was iffy," she said. The Celexa and two other prescriptions have been filled regularly by crossborderpharmacy.com at a total cost of $364 every three months - well below the $540 she would pay at home, Hammerquist said.

Reduced supplies of drugs from the four companies has forced Canadian Internet pharmacies to seek alternative sources, usually other Canadian operations willing to sell their stocks at a profit. That raises the price for U.S. customers.

"CanadaMeds' Glaxo products have gone up 28 percent in price since the freeze," Jorgenson noted. Andy Troszok of the Canadian International Pharmacy Association said smaller operators had failed, and the situation was "threatening to the industry as a whole."

While the drug companies cite safety concerns in their decisions, saying Americans cannot trust the quality of the Canadian drugs, the pharmacies say the companies only want to protect profit margins. "Pfizer's not concerned about the safety of a patient in Ohio who will run out and can't afford to resupply at an American pharmacy," Jorgenson, of CanadaMeds.com, said. "We've been doing this for four years as an industry across Canada. Nobody's been killed."

At its height, Canada's Internet pharmacy industry had revenue of more than $600 million a year. Canadian drugs are cheaper because of government price controls, and the businesses flourished as drug prices in America skyrocketed.

It is illegal to import drugs from Canada, but the U.S. Food and Drug Administration has allowed the mail-order service direct to customers under a "compassionate non-enforcement" policy to help Americans unable to afford the higher-cost medicine at home.

Also, the U.S. House of Representatives recently passed a bill allowing the reimportation of drugs manufactured in the United States, which would permit the sale of less-expensive products from Canada. A Senate version of the measure is more restrictive, and tough negotiations on a compromise version are expected in coming months.

Meanwhile, the drug companies continue to argue that the restrictions make good business and public policy. Some have said the Internet pharmacies that sold to Americans were reducing the amount of drugs available for Canadians - a concern shared by many Canadians.

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Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Mary A. Dickson, Associate Executive Director MAD

DATE: July 30, 2003

RE: Actions Against Organizations Facilitating Importation of Canadian Medications

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Attached is an updated Excel spreadsheet listing the most recent information that NABP has received from the Boards of Pharmacy concerning informal and formal actions that state, federal, and other regulatory agencies have initiated against storefronts, pharmacies, and other groups and individuals who facilitate or otherwise assist in the illegal importation of unapproved prescription medications from Canada.

Please feel free to continue providing us with additional information as it becomes available so that we can add the data to our spreadsheet and periodically provide the Boards of Pharmacy with updates.

Thank you for your assistance in compiling this table.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Moira Gibbons, ELTP/VIPPS Manager
Melissa Madigan, Professional Affairs Manager

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AK	**7/1/03** - No actions have been initiated to date.		
AL	**3/20/03** - AL BOP filed a complaint against **Discount Drugs of Canada (DDC)** and its owner/operators, Timothy Morton & Steve Reese, in the Circuit Court of Jefferson County, seeking a temporary restraining order (TRO) as well as preliminary & permanent injunctive relief, due to allegations that it is, among other things, engaging in the unauthorized practice of pharmacy in AL. The TRO was granted by the court the same day of the filing, and the Board immediately enforced the order, shutting down DDC. **3/31/03** - Circuit Court of Jefferson County issued an order extending a previously entered TRO against DDC, until further court order. **6/30/03** - Board's request was granted and a circuit court issued a temporary restraining order against **Canadian Discount Drugs**. A hearing on the Board's request for a preliminary injunction is scheduled for July 8, 2003.	**6/03** - FDA issues warning letter to staff of **CanadianDiscountDrugs** and **Ameri-Can Global Pharmaceutical Supply, Inc**, in Ozark, AL, which assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
AR	**3/03** - BOP issued a warning letter to **RxDepot/www.therxDepot.com,** Lowell, AR, a company that facilitates US consumers obtaining Canadian prescription medications.	**3/21/03 - (RxDepot/www.therxDepot.com)** - the **FDA** issued a warning letter to the company, located in Lowell, AR, notifying the firm that the agency considered the firm's operations to be illegal and a risk to public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. FDA is also acting in conjunction with AR BOP action. **3/27/03 – FDA issued a statement** strongly supporting the filing by the OK SBOP & the OK AGO of a petition for injunction seeking to stop the **RxDepot** storefront pharmacy from violating state law. **4/10/03** - the **Manitoba Pharmaceutical Association** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy,** 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreements with **RxDepot** in any state. **RxDepot** is operating in AR in violation of the state law, and they have been given direction from the State Board of Pharmacy to cease its operation.	

[Shaded areas designate new or updated information since the June 2003 report.]

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AZ	**2002-2003** - Seven (7) Canadian pharmacies applied for noresident pharmacy permits. The Board requested information on how they would comply with FDA regulations on importation. None of the applicants has responded; their applications have been deemed incomplete. **5/9/03** - AZ BOP issued a letter to the AZ Better Business Bureau asking it to warn consumers about the risks of purchasing prescription drugs illegally from Canada and other foreign countries. The letter cited the sentencing of Rory Dannenberg, operator of **Value Prescriptions** located in Phoenix, AZ, for an unrelated felony conviction. Dannenberg is one of several illegal Canadian prescription service operators being investigated by the Board for offering prescription drugs for sale without a pharmacy permit and without a licensed RPh in place.		
CA	**7/1/03** - No actions have been initiated to date.		
CO			
CT	**7/2/03** - No actions have been initiated to date.		
DC			
DE	**1/8/03** - At its January board meeting, the Board voiced its concerns and strong opposition to the importation of medications from Canada. The Board formalized its concerns in a letter encouraging NABP to oppose this activity.		
FL	**8/02** – Board denies a nonresident pharmacy license to a Canadian pharmacy: statutes require that the B4pharmacy be located in a US state. **12/02** – FL Board attorney issues legal opinion stating businesses that assist people in importing prescription medications should be treated like pharmacies because they lead to prescriptions being dispensed.		
GA		**6/03 - FDA** issues warning letter to President/CEO of **CanadianDiscountDrugs** in Peachtree City, GA a business that assists US consumers in obtaining prescription drugs from Canada, specifically **Total Care Pharmacy** in Calgary, Alberta, CAN.	
GU			
HI	**7/03** - No actions initiated to date.	**6/03** - Pending.	
IA	**6/03** - Board sent a C&D letter to Nuway Drug.		
ID			
IL			

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
IN	**6/03** - Board has filed complaints with the Attorney General of IN.		
KS			
KY			
LA	**9/02** - Cease and Desist Notification sent to FNC **Canadian Discount Medication** of Monroe, LA. **3/19/03** - Cease and Desist Notification sent to **Prescription Referral Services** of Monroe, LA.		
MA	**7/03** - Board has been closely monitoring the issue and has been providing info to the Office of the Attorney General.		
MD			
ME			
MI			
MN	**7/2/03** - No actions initiated to date.		
MO	**7/2/03** - No actions initiated to date.		
MS	**7/2/03** - No actions initiated to date.		
MT	**3/03** – Board issued an official complaint against **RealFast Drug Store**, known as **RF Drug Store** (www.realfastdrugstore.com), located in Manitoba, CAN. **RF Drugstore** has entered into an arrangement with Club Medz, a storefront located in Great Falls, MT. Board also intends to take **Club Medz** to court within a month if they do not comply with their order to cease and desist, and have been working with the **FDA** in hopes of obtaining the involvement as well. **4/03** – Board investigated **Club Medz**, issued a subpoena, and **Club Medz** ceased operations at the end of the business day on 4/10/03. Board had charged that the lay people manning the storefront were engaged in the unlicensed practice of pharmacy and that they were aiding and abetting an illegal act. **4/03** - Board issued a complaint against **Real Fast Drugstore** (aka **R.F. Drugstore**) with the Manitoba Pharmaceutical Association. The matter is still under MPA's consideration.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
MT	**Spring '03** - Several C&D letters sent to Canadian mail order pharmacies. **5/03** - Denied an out-of-state mail service pharmacy license to Canadian pharmacy on grounds that the Board is unable to license an entity to perform an illegal act. **5/03** - Contacted both a RPh & a layperson seeking to open storefront operations, counseling the RPh not to aid and abet illegal activity or face disciplinary action. The layperson was told that the Board would consider her to be engaged in the unlicensed practice of pharmacy and aiding and abetting an illegal act. So far, neither operation has begun. **6/03** - Began action against a new **Rx Depot** in Billings, MT, and will follow the same rationale as previously used in the **Club Medz** case. Informed the FDA of the situation via phone. **6/03** - Issued a C&D letter to the Billings Gazette, a state newspaper running a full-page ad for **Canada Discount Rx**, on the grounds that they are aiding and abetting an illegal act. The ad appeared in the June 18, 2003 issue. **7/31/03** - Board filed a petition in district court seeking injunctive relief against **Sandra S. Kennedy d/b/a Rx Depot.** The Board seeks a temporary restraining order barring **Kennedy/Rx Depot** from conducting any type of "prescription service," among other things.		
NC	**6/11/03** - the NC BOP announced the issuance of Cease & Desist Orders for 5 businesses that are forwarding prescriptions to Canada to be filled and returned to the US. Orders were sent to: **Discount Drugs of Canada**, Gastonia NC; **Canada Drug Outlet, Inc**, Concord, NC; **Rx Price is Right, Inc**, Winston-Salem, NC; **Canada Drugs**, Asheboro, NC; and **Prescription Care of NC**, Banner Elk, NC. **7/14/03** - Per Carlson Carmichael, lawyer for the NC BOP, as of mid-June 2003, they have sent C&Ds to 6 locations in NC that are storefront-type operations. They are close to taking the next step, although the Board needs to give the final approval, which would be an action or actions for injunction in court against the locations.	**7/1/03 - FDA** issues a letter supporting the Board's efforts to stop businesses that forward prescriptions to Canada to be filled by Canadian pharmacies for U.S. consumers, and the FDA offers its assistance in the Board's efforts to stop such businesses.	

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
ND	**Fall 2002** – BOP has sent numerous cease and desist orders to Canadian and other international pharmacies that ship into ND.		
NE			
NH	**7/2/03** - No actions initiated to date.		
NJ			**5/12/03** - New Jersey Legislature bill No. 570 Section 34 (b) addressing pharmacists was amended to prohibit the shipping of Canadian and unapproved meds to NJ. **5/22/03** - amendment prohibiting the shipment of Canadian/unapproved meds was dropped.
NM			
NV			**5/03** - Law enacted making it unlawful to fill prescriptions via the Internet, using illegally imported medications, or to assist one in doing so.
NY	**7/03/03** - Investigations have been initiated.		
OH	**11/00** – Cease and desist order issued against **Provincial Pharmacy, Inc**, in Windsor, Ontario, CAN. Basis: unlicensed shipping of prescriptions to OH residents.		
OK	**3/27/03** – The state authorities filed a petition in OK state court alleging that **RxDepot** is illegally operating an unlicensed pharmacy. **6/3/03** - State court granted a temporary restraining order against **RxDepot** which becomes effective on approximately 8/31/03 so that **RxDepot** may appeal the order. Judge's order stated **RxDepot** violated state statutes.	**4/10/03** - the **Manitoba Pharmaceutical Association (MPA)** in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of **Northgate Clinic Pharmacy**, 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The MPA received a copy of the court document filed in the District Court of OK (case # CJ-2003-2643) describing the conduct of **RxDepot** in the state of OK being in violation of state law. The warning letter states that **Northgate Clinic Pharmacy** must immediately cease business agreements with **RxDepot** in any state and the shipment of medication into the state of OK.	
OR	**7/2/03** - No actions have been initiated to date; however, the Board has ongoing investigations.		
PA			
PR			

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
RI	**2002-** Cease and desist order sent to two Manitoba pharmacies. Complaint sent to MB pharmacy regulators regarding MB pharmacies shipping to RI.		**2/03** – Legislation introduced to **allow** Canadian pharmacies to ship prescription meds to RI. Legislation, backed by RI Medical Society, would allow BOP to license CAN pharmacies. BOP ED Cordy said Board would oppose the bill.
SC			
SD	**2002-2003** – Board has sent cease and desist letters and has phoned Canadian pharmacies to inform them of their illegal shipping of meds into SD. **2002-2003** – Complaint sent to MB pharmacy regulator concerning MB pharmacies shipping to SD residents.		
TN	**10/02** – State sent cease and desist order to **CanadaDiscountRx**. **1/03** - C&D letter sent to **Canadian Rx Consultants Group**, Maitland, FL. No response. **3/03** - C&D letter sent to **Canadian Drugs2U**, Nashville, TN. No response yet; Board is considering next action. **4/03** - C&D letter sent to **Global Pharmacy Rx**, Cookeville, TN. Owner advises that they are no longer in business. **5/03** - Board decides that facilitating the importation of Rxs for Canadian pharmacies is the practice of pharmacy and storefronts should be licensed. **5/03** - C&D letter sent to **Medi Save**, Knoxville, TN. Attorney for the owners of **Medi Save** advises that they are no longer in business. **5/03** - C&D letter sent to **RealFast** of Winnipeg, Manitoba, CAN. **6/03** - C&D letter sent to **Canada Direct Pharmacy, LTD**, in Calgary, Alberta, CAN. No response.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
TX	**7/03** - The Board will send C&D letters to any facilitators who receive or process prescriptions, and any person or business that uses the word "pharmacy," or graphical representations of the same. **7/3/03** - TX SBOP mailed nine (9) C&D letters. A 10th C&D letter will be mailed soon.		
UT	**7/02** - C&D Order issued to **Rx North America**. **4/03** - C&D Order issued to **Discount Prescription Service**, a facilitator. **4/03** - Complaint filed with the **College of Pharmacists of British Columbia** against a BC pharmacy that appeared to be shipping prescriptions into UT. **4/03** - Complaint filed with the **College of Physicians and Surgeons of British Columbia** against a doctor allegedly prescribing medications for export to UT.		
VA			
VI			
VT	Foreign Prescription Drugs" is published in the Vermont Board of Pharmacy Newsletter. **7/03** - The Board currently has two (2) investigations open regarding Canadian internet pharmacies. The allegations are: one is a storefront, the only one believed to be in VT; and the second involves a firm that has come to VT, advertised a "Canadian Drug" seminar, and had a pharmacist representing the company at the conference. Both investigations are still open.		VT has new rules in the legislative process, slated to go into effect **8/1/03**. In the new rules, any pharmacy that ships meds into VT must be licensed by the state and have one RPh licensed in VT.
WA	Several letters have been sent advising Canadian pharmacies not to ship to residents of WA.		
WI	**7/7/03** - There is one case pending which is against **Philip D. Kuehnl** and **Premium Discount Pharmaceutical Services**.		
WV	**5/13/03** - Cease and desist letter sent to **Discount Prescription Center of WV**, a storefront. **Discount Prescription Center** filed an action in court to bar authorities from closing it, claiming it is not a pharmacy.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
WY	**6/3/03** - Board sent cease and desist letter to **Canada Direct Pharmacy** in Calgary, Alberta, CAN, which sent advertising to St Anthony Manor. **7/03** - Board sent a cease and desist letter to **ThriftMedsNow Pharmacy** in Manitoba, CAN, due to its being an unlicensed pharmacy that is advertising in a Wyoming paper.		
	FEDERAL ACTIONS		
	FDA - Cyber Warning Letters to Canadian Pharmacies		
	10/31/01 - www.RxNorth.com; www.OnlineCanadianDrugstore.com (MediPlan)		
	10/31/01 – www.Canadameds.com (Point Douglas Pharmacy)		
	11/15/01 – www.Canadarx.net (Target Zone)		
	ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES		
	May 2002 - The **Ontario College of Pharmacists**, the regulatory body for enforcing pharmacy practice standards, charged **The Canadian Drugstore, Inc**, with 15 different violations, including operating an unlicensed Internet pharmacy without registered pharmacists from November 2001 to February 2002.		
	March 2003 – Cross-Border Statement was issued by **Nova Scotia College of Pharmacists** stating, among other things, that Nova Scotia pharmacists and pharmacies should not participate in any scheme or service to accommodate importation of Canadian medications by US citizens. Pharmacists/pharmacies that accommodate such services may be found to be practicing unethically and may be found guilty of professional misconduct.		
	April 2003 – Canadian Broadcasting Corporation (CBC), Fredericton – The **New Brunswick College of Physicians** has suspended the license of **Dr Andre Loiselle**, a physician accused of helping to sell prescription drugs over the Internet. **Dr Loiselle** wrote prescriptions for a Web site that markets drugs to senior citizens in the US, even though he		
	April 2003 - The **Manitoba Pharmaceutical Association (MPA)** in Winnipeg, Manitoba, CAN sent a "warning letter" to **Derek Chan**, Pharmacy Mgr of **Northgate Clinic Pharmacy.** The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreement with **RxDepot** in any state and the shipment of medication into the state of OK.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS

Information obtained between May 2003 - July 2003

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation

ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES, CONTINUED

July 2003 - The **Ontario College of Pharmacists (OCP)** resolved its prosecution against **The Canadian Drugstore Inc**; **Rep-Pharm, Inc**; **Stephen Bederman, RPh**; and **Dr Stanley Gore** and his company **Canadian Custom Prescriptives, Inc.** Summary of charges involved: unlawful dispensing or selling of a drug to a patient; operating an unlicensed pharmacy; and dispensing a prescription without written authorization of a Canadian doctor. The specific judgments follow:

- **The Canadian Drugstore, Inc,** pled guilty on 6/23/03 to one offense contrary to the Regulated Health Profession Act, 1991 (RHPA), and four charges contrary to the Drug & Pharmacies Regulation Act (DPRA).
The Ontario Court of Justice fined the company (**Canadian Drugstore, Inc**) $20,000. This fine amount was part of an overall disposition that included a $125,000 payment by the **Canadian Drugstore, Inc,** to the Leslie Dan Faculty of Pharmacy, University of Toronto, to establish the Ontario College of Pharmacists' Professorship in Pharmacy Practice.
- **Rep-Pharm** was fined $5,000.
- Charges against the **RPh Bederman, Dr Gore**, and affiliated companies were dropped; however, the pharmacist faces a disciplinary hearing in December 2003, and the doctor was referred to the College of Physicians and Surgeons of Ontario for a hearing and determination.

[Shaded areas designate new or updated information since the June 2003 report.]

Agenda Item B

State of California Department of Consumer Affairs

Memorandum

To: Patricia Harris
Executive Officer

Date: July 15, 2003

From: Paul Riches

Subject: Statutory History for B&P 4343

Business and Professions Code 4343 establishes a prohibition on the use of signage that includes words such as "pharmacy," "drugstore," "apothecary," or words of similar import unless the premise is a licensed pharmacy.

> 4343. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110.

History

The origin of this prohibition is found in a 1905 statute (Chapter 406) that established a general regulation of pharmacists. The following was included in Section 1 of that act:

> "Every store or shop where drugs, medicines, or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs," or any of these words, or the characteristic showbottles or globes, either colored or filled with colored liquids, shall be deemed a "pharmacy" within the meaning of this act."

This provision essentially brings existing "pharmacies," by whatever name, under the board's regulatory authority. This is an inclusive statute designed to assert the board's jurisdiction over existing businesses.

The 1905 statute was amended in 1927 (Chapter 599) to that adds a prohibition on the use of "drug" or "drugs" in advertisements or displays in businesses that were not operated by a pharmacist.

> "Every store or shop where drugs, medicines, or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drugstore," "drugs," or any of these words, or the characteristic showbottles

> or globes, either colored or filled with colored liquids, shall be deemed a "pharmacy" within the meaning of this act, and no store or shop shall use the word drug or drugs in any advertisement, or display unless a licentiate is in charge."

The 1907 statute was entirely rewritten in 1937 (Chapter 399) in a bill that codified the Pharmacy Law in the Business and Professions Code. The restrictions that were established in the 1905 and 1927 statutes were split into sections 4035 and 4037. This statute did not make substantive changes to these provisions. The 1937 statute also directly defined "pharmacy" for the first time and established a registration scheme for pharmacies. Prior legislation simply required that each store providing drugs was subject to the board's jurisdiction and must be in the charge of a pharmacist.

> 4035. As used in this chapter, pharmacy means and includes every store or shop where drugs, medicines or chemicals are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," or any of these words.
>
> 4037. No store or shop shall use the words "drug" or "drugs" in any advertisement or display unless a registered pharmacist or a licentiate is in charge.

The addition of "licentiate" is not substantive in the context of this history. The 1937 statute draws a distinction between pharmacists licensed prior to its implementation and those licensed after. A "registered pharmacist" described pharmacists licensed under the apprentice system that existed prior to 1937 and a "licentiate in pharmacy" generally was a pharmacist licensed based on a licensing scheme much like the one that exists now for pharmacists (formal education, experience, and board examination).

Sections 4035 and 4037 were amended in 1947 (Chapter 931) to add the words denoting pharmacies in Section 4035 as reserved names that may only be used by a pharmacy. These amendments mark a change from an inclusionary statute defining pharmacy to an exclusionary statute that reserved use of those names for licensees.

> 4035. As used in this chapter, "pharmacy" means and includes every store or shop where drugs, medicines or medicinal poisons ~~chemicals~~ are dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded, which has upon it or in it as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," "drug sundries," "prescriptions," or any of these words, or any combination of these words.
>
> 4037. No store or shop shall use any ~~the~~ words or combination of words enumerated in Section 4035 ~~"drug" or "drugs"~~ in any advertisement or display unless a registered pharmacist or a licentiate is in charge.

The Pharmacy Law was substantially revised in 1955 (Chapter 550) to make minor changes in Section 4035 defining "pharmacy" and moved the prohibition formerly contained in Section 4037 to Section 4391.

> 4035. As used in this chapter, "pharmacy" means and includes every store or shop where drugs~~, medicines~~ or medicinal poisons are dispensed or sold at retail~~,~~ or displayed for sale at

retail, or where prescriptions are compounded, which has upon it or in it, as a sign the words "pharmacist," "pharmaceutical chemist," "apothecary," "druggist," "pharmacy," "drug store," "drugs," "drug sundries," "prescriptions," or any of these words, or any combination thereof. ~~of these words.~~

4391. No store or shop shall use any words or combination of words enumerated in Section 4035 in any advertisement or display unless a registered pharmacist ~~or a licentiate~~ is in charge.

In 1965 (Chapter 1822) Section 4035 was entirely rewritten to define "pharmacy" as a place or premise licensed by the board as a pharmacy. The new section also exempted hospitals from licensure as pharmacies and defined narcotics. All reference to reserved words was eliminated in this rewrite of Section 4035.

Section 4391 was rewritten by the same bill to eliminate reference to Section 4035 and to enumerate and expand words reserved for pharmacies to words of similar import and symbols denoting a pharmacy.

~~4391. No store or shop shall use any words or combination of words enumerated in Section 4035 in any advertisement or display unless a registered pharmacist is in charge.~~
4391. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (℞) or similar design, unless there is upon or within the building a pharmacy holding a permit issued by the board pursuant to Section 4080 of this code.

In 1996, Section 4391 was moved and subject to technical amendments in Assembly Bill 2802 (Chapter 890, Statutes of 1996). This legislation was a comprehensive reorganization of the Pharmacy Law and moved the provisions of Section 4391 to Section 4343.

4343. No building shall have upon it or displayed within it or affixed to or used in connection with it a sign bearing the word or words "Pharmacist," "Pharmacy," "Apothecary," "Drugstore," "Druggist," "Drugs," "Medicine," "Medicine Store," "Drug Sundries," "Remedies," or any word or words of similar or like import; or the characteristic symbols of pharmacy; or the characteristic prescription sign (Rx) or similar design, unless there is upon or within the building a pharmacy holding a license issued by the board pursuant to Section 4110 ~~4080 of this code~~.

Agenda Item C

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date:** **September 3, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Proposed Citation and Fine for Statute for Wholesale Violations and Proposed Regulations Regarding Wholesale Drug Transactions**

At the last Enforcement Committee meeting, Supervising Inspector Judi Nurse gave an overview regarding bid contract diversion in California. Pharmacies purchase "bid contract" drugs at special prices and then through a common ownership transfer the drugs to its wholesale facility to be resold to other wholesalers. Often times, there is no record for these drug transaction. The drugs are resold several times through many wholesalers and many states in largely undocumented transactions that are impossible to trace. This "gray market" system has allowed for counterfeiting which is the dilution, mislabeling or adulteration of the drug. The unscrupulous companies can turn one shipment of injectable medications into many by watering down the drugs and reproducing the packaging.

The issue of bid contract diversion and the proliferation of counterfeit drugs have caused the committee to propose regulations to ensure the integrity of California's drug distribution system. The committee discussed the regulation proposal at its last meeting and comments were made that the regulation would impede legitimate business transactions and modifications were suggested. It was also stated that the PDMA allows for intra-company sales, which may be contrary to the proposal. While the board had been using Nevada as its model for the regulatory framework, it was suggested that the committee might want to review the Florida legislation. This new legislation identifies a list of drugs that requires due diligence in authenticating prior transactions on pedigrees.

Chair John Jones requested interested parties to submit proposed language to address their concerns; however, none were provided. Therefore, staff prepared a new regulatory proposal to address wholesale and pharmacy transactions. In addition, a legislative proposal was prepared for citation and fine authority for wholesale violations.

Board of Pharmacy
Draft Changes for Wholesale Violations
August 22, 2003

Add Section 4168 to the Business and Professions Code, to read:

4168. (a) No person or entity shall:

(1) Purchase, trade, sell or transfer dangerous drugs or dangerous devices at wholesale from a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell or transfer counterfeit drugs or devices.

(3) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(4) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

Board of Pharmacy
Proposed Additions
Title 16 - California Code of Regulations

1784. Wholesale Drug Transactions

(a) A wholesaler shall generate an invoice for each sale, trade or transfer of a dangerous drug or a dangerous device. The invoice shall include the lot number of the dangerous drug or dangerous device.
(b) A dangerous drug or dangerous device may only be sold, traded or transferred three times before being furnished to the final consumer. A wholesaler shall implement procedures to reasonably ensure that it does not sell, trade, transfer or purchase dangerous drugs or dangerous devices that have been sold, traded or transferred in violation of this section.
(c) The sale, trade or transfer of a dangerous drug or dangerous device between licensees with the same ownership are not subject to subdivision (b).
(d) Subdivision (b) shall not apply to expired dangerous drugs or dangerous devices or to dangerous drugs and dangerous devices that have been returned after they have been dispensed.

1785. Pharmacy Drug Transactions

A pharmacy shall may only sell a dangerous drug or dangerous device to a patient pursuant to a prescription, to the wholesaler that sold the dangerous drug or dangerous device to the pharmacy, or to another licensee with the same ownership.

Agenda Item D

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: September 4, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **MBC/Board of Pharmacy Joint Task Force on Prescriber Dispensing – Proposed Statutory Language to Authorize Dispensing by Medical Groups**

As reported at the last Enforcement Committee and board meeting, the Medical Board of California and the Board of Pharmacy held a joint task force meeting on the issue of prescriber dispensing. The meeting was held on May 27, 2003, and the task force reached consensus on the following: (1) Under current law, an individual prescriber can own his/her own prescription stock and dispense to his or her own patients as specified and such practice should be allowed to continue with the goal of strengthening and educating prescribers regarding the recordkeeping requirements; (2) Allow a medical group to dispense prescription medications pursuant to a special permit issued by the Board of Pharmacy and specified conditions that require one physician from the medical group to be responsible and accountable for the security of the prescription medications, recordkeeping requirements, and a consultant pharmacist reviews the dispensing process; (3) Establish the authority for a pharmacy to place an automated dispensing device in a prescriber's office; and (4) Provide for joint oversight by the appropriate licensing agencies.

The task force agreed that staff from the two boards would work together to draft language for each board to consider as a possible joint legislative proposal for 2004. Draft language was developed and the Medical Board task force members provided comments on the draft. The language was reworked to address their comments (draft 2). As you will note, the proposal would require a special clinic licensure for these group practices, which would have a fiscal impact to the board.

Requested Action: The Enforcement Committee needs to decide what action if any to recommend to the board. Are there other amendments that the committee would like to add? Does the committee want to recommend that the board support the proposal as its position regarding dispensing by medical groups?

STATE OF CALIFORNIA -- STATE AND CONSUMER SERVICES AGENCY GRAY DAVIS, Governor

Consumer Affairs

MEDICAL BOARD OF CALIFORNIA
EXECUTIVE OFFICE
1434 Howe Avenue, Suite 92
Sacramento, CA 95825-3236
(916) 263-2389 FAX (916) 263-2387
www.medbd.ca.gov

August 26, 2003

Patricia Harris
Executive Officer
Pharmacy Board of California
400 R Street
Sacramento, CA 95814

Dear Ms. ~~Harris~~ Patty:

Thank you for sharing the draft proposed language that would modify existing law as it relates to prescriber dispensing of pharmaceuticals. Dr. Steven Rubins and Ms. Lorie Rice, Members of the Joint Task Force on Prescriber Dispensing representing the Medical Board of California, have had the opportunity to review this language and wish to provide their observations. First, it is their belief that this language substantially achieves the goals that the Task Force set out in its meeting of May 27, 2003. Specifically, the addition of proposed Business & Professions Code Section 4180, (G) A group practice, addresses the need to recognize the advantages to patients of making pharmaceuticals available in the modern medical office. They wish to express their appreciation for the work that you have done to bring this issue so far along.

As the Board of Pharmacy's Enforcement Committee considers the language that you have prepared, the Medical Board wishes to offer the following observations:

1. Current law requires physicians to maintain a drug log and a competent medical record that enables the auditing of their dispensing and management of pharmaceutical products within their practice. Your proposed language [Section 4170(d)] would add new specifics to that requirement that would apply not only in the group practice environment that was discussed at the Task Force meeting, but to all physicians who dispense drugs in their practice. Since the need for these enhanced record-keeping requirements was not a matter of extensive discussion before the Task Force, the Medical Board is not certain what problem has been identified with the current practices of independent prescribers that is being addressed by this language. We are concerned that adding new requirements for every physician, in the absence of an identified problem, is unnecessary and will make passage of a proposed bill problematic.

2. The proposed definition of a "group practice" [Section 4180(c)] suggests that all physicians who are affiliated with a group practice must manage their dispensing practices through the standards established in Section 4182(a)(2). In reality, some

physicians who participate in a group practice may not wish to affiliate with other members of that practice as it relates to dispensing procedures. In the event that a single physician in a group practice chooses to manage their dispensing practices independently, we propose that this be accommodated by addition of the following sentence to 4180(c): This section shall apply only to those licensees of the group who also participate in the dispensing practices of the group.

We would also like to raise some additional considerations that may call for clarification through additional language. The first matter relates to some confusion that may be created by Sections 4170(a)(1) and 4170(a)(8). Section 4170(a)(1) states that a nurse or physician "attendant" may not furnish dangerous drugs. Section 4170(a)(8) says that a nurse or a physician "assistant," operating under standardized procedures, may hand prescription drugs to a patient. It is unclear whether the physician attendant is a classification different than that of physician assistant under the law, and if there is a legal distinction between the words furnish and hand. We believe that, over time, these have taken on a common meaning, but there may now be an opportunity for us to provide greater clarity in the law. This becomes important because the modern medical practice recognizes the great range of supportive services that are performed by nurses and physician assistants under standardized procedures. These services can include providing pre-packaged drugs to a patient and patient consultation designed to improve compliance with treatment objectives. This aim is further supported in your proposed Section 4181(a)(2). Therefore, it is important that physicians know precisely the scope of responsibilities that can be delegated to these personnel under written protocol.

The second issue that we would raise for your consideration is to emphasize that a consumer should ultimately be both safeguarded and provided an advantage by the expanded dispensing options that are being made available. Whenever the prescriber is also the seller of the product, it is imperative that the consumer realize that they have options available to them regarding whether or not to purchase the drug in the physician's office. Section 4170(a)(6) and (7) requires the prescriber to offer a written prescription and to provide written disclosure to the patient concerning that choice. We believe that this should be emphasized as well as strengthened. It is believed that this can be accomplished by amending Section 4170(a)(7) to add the statement: This disclosure shall contain information relating to the availability of generic drug alternatives and information that cost savings may be available through purchase at a pharmacy.

Thank you for your consideration of the views expressed in this letter. Ms. Rice, Dr. Rubins and I are available to discuss any of these issues further and look forward to working with you to implement the work of the Task Force.

Sincerely,

Ron Joseph
Executive Director

Board of Pharmacy
Prescriber Dispensing Reform
Concept Draft – June 10, 2003

Article 12 – Prescriber Dispensing

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or a physician assistant who functions pursuant to Section 3502.1, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice dentistry, or a certificate to practice podiatry, and who is duly registered as such by the Medical Board of California, the State Board of Optometry, the Dental Board of California, or the Board of Osteopathic Examiners of this state.

(d) The prescriber shall maintain the following information for each prescription on file and this information shall be readily retrievable:

(1) The date dispensed, and the name or initials of the dispensing prescriber.

(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label.

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing prescriber.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.

4171. (a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.
(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, to veterinarians furnishing drugs for the treatment of animals, to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

4172. A prescriber who dispenses drugs pursuant to Section 4170 shall store all drugs to be dispensed in an area that is secure. The Medical Board of California shall, by regulation, define the term "secure" for purposes of this section.

4173. This chapter does not prevent the dispensing of drugs or devices by registered nurses functioning pursuant to Section 2725.1.

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1, or the order of a pharmacist acting under Section 4052.

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, or physician assistant pursuant to Section 4170.
(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

Article 13 – ~~Non-Profit or Free~~ Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a prescriber ~~physician~~, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.
(G) A group practice.
(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.
(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued ~~to a specific clinic and~~ for a specific location.
(c) For the purposes of this article, "group practice" means more than one prescriber operating a practice providing health care services at a specific location.

4181. (a) (1)Prior to the issuance of a clinic license authorized under Section 4180 (a)(1)(A) – (F), the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.
(2) Prior to the issuance of a clinic license authorized by 4180(a)(1)(G), the group practice shall comply with all applicable laws and regulations relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist and the professional director of the group practice.
(b) ~~These~~ The policies and procedures required by this section shall include a written description of the method used in developing and approving them and any revision thereof.
(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
(b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article. The clinic shall maintain these written certifications in the clinic for at least three years.~~, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.~~
(c) For the purposes of this article, "professional director" means a ~~physician~~ prescriber acting in his or her capacity as ~~medical~~ professional director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).

4184. ~~No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.~~ Clinics that dispense Schedule II and Schedule III controlled substances shall report those prescriptions to the CURES program pursuant to Section 11165 of the Health and Safety Code.

4185. The board, and any other authorized officer of the law, shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug delivery system is ~~being~~ used.
(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

4187. (a) Notwithstanding any other provision of law, an automated drug delivery system located in a clinic licensed pursuant to Section 4180(a)(1)(G) shall be owned and operated by a licensed pharmacy.
(b) Notwithstanding any other provision of law, a pharmacist may supervise a single pharmacy technician at a remote location where an automated drug delivery system is operated in a clinic licensed pursuant to Section 4180(a)(1)(G), and this pharmacy technician shall not be subject to the ratio established in Section 4115.

Agenda Item E

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: September 4, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Medication Shortages and Limited Distribution Practices of Manufacturers and the Impact on Public Health**

Board member Stan Goldenberg requested that this topic be discussed at an Enforcement Committee meeting. His request was based on a Citation and Fine Committee's review of a consumer complaint regarding the inability of a pharmacy to fill the patient's prescription because the pharmacy didn't have the medication due to a manufacturer's shortage.

A patient had filed a complaint with the board against a pharmacy for not providing her with all the Enbrel that she was prescribed. The pharmacist only dispensed 4 kits instead of the 8. The pharmacist informed the patient that he was unable to fill her entire prescription due to a shortage of the medication. The patient was upset because she specifically had registered with the drug manufacturer to avoid such situations. The manufacturer assured her that they were sending the pharmacy her entire order. The patient felt that the pharmacy was giving her medication to other patients.

In this specific case, the complaint was closed with no further action.

It appears that the National Association of Boards of Pharmacy (NABP) has appointed a task force to address this issue and will be meeting in November.

National Association of Boards of Pharmacy
700 Busse Highway • Park Ridge, IL 60068
Tel: 847/698-6227 • Fax: 847/698-0124
Web Site: www.nabp.net

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

DATE: August 8, 2003

RE: 2003-2004 Committee and Task Force Appointments

President Donna Wall has finalized her appointments for the Committees and Task Forces for the 2003-2004 year. For your information, the list of appointments is attached.

If you should have any questions or need additional information, please feel free to contact me.

CC/cs
Attachment

cc: Executive Committee

2003 – 2004
COMMITTEE AND TASK FORCE APPOINTMENTS

GOVERNMENT AFFAIRS SUBCOMMITTEE
SEPTEMBER 12, 2003
Charge: Study the feasibility and possible action plan for mandating that indications for medication therapy be included on all prescriptions and prescription orders unless there is a medically necessary or legal reason requesting that this not occur.

Chair	Charles R. Young	Board Executive	MA	I
	Lawrence H. Mokhiber	Board Executive	NY	II
	Oren M. Peacock, Jr.	Chain	TX	VI
Ex- Officio Members	Susan DelMonico	Community Chain	RI	I
	Betty H. Dennis	Hospital	NC	III
	Richard A. Palombo	Community	NJ	II
Alternates	Juluette Bartlett-Pack	Consumer	TX	VI
	Randolph A. Harrop	Chain	WY	VII

TASK FORCE ON LIMITED DISTRIBUTION AND SHORTAGE OF MEDICATIONS
NOVEMBER 19-20, 2003
Charge: Examine the scope of medication shortages and imposed limited distribution policies of manufacturers and impact on these practices on the availability of medications and protection of the public health.

Chair	Jennifer S. Nevins	Hospital	WY	VII
Members	Timothy Armstrong	Chain	KY	III
	James T. Carder	Board Executive	WY	VII
	Elwin D. Goo	Hospital	HI	VIII
	Sophie Heymann	Consumer	NJ	II
	Sheila L. Mitchell	Hospital	TN	III
	William T. Winsley	Board Executive	OH	IV
Alternates	W. Michael Brimberry	Hospital	TX	VI
	Elizabeth I. Gregg	Hospital	OH	IV
EC Liaison	Oren M. Peacock Jr.	Board Executive	TX	VI

COMMITTEE ON LAW ENFORCEMENT/LEGISLATION
DECEMBER 10-11, 2003
Charge:

1. Review and comment on existing legislation and rules for the practice of pharmacy, legal distribution of drugs, and related areas within pharmacy, including impaired pharmacists;
2. Develop model regulations for pharmacy as assigned by the Executive Committee, or from resolutions adopted by the members of the Association, or from reports of the other committees of the Association; and
3. Recommend to the Executive Committee areas where model regulations are needed in pharmacy for improving the protection of the public health.

Chair	Rebecca Deschamps	Board Executive	MT	VII
Members	Joseph L. Adams	Chain	LA	VI
	Joshua Bolin	Board Executive	IN	IV
	Philip P. Burgess	Chain	IL	IV
	Julie D. Frazier	Community	TN	III
	Marilyn M. Silcock	Hospital	ID	VII
	Richard R. Smiga	Chain	PA	II
Alternates	Jeanne Gilligan Furman	Hospital	MD	II
	Karen Ryle	Community	MA	I
EC Liaison	Howard C. Anderson, Jr.	Board Executive	ND	V

COMMITTEE ON CONSTITUTION AND BYLAWS
MARCH 12, 2004
Charge:
Defined by the Constitution and Bylaws

Chair	Jerry Moore	Board Executive	AL	III
Members	Reginald B. Dilliard	Community	TN	III
	David Flashover	Healthcare	NY	II
	Lloyd K. Jessen	Board Executive	IA	V
	Richard J. Oubre	Chain	LA	VI
Alternates	George L. Bowersox	Chain	NH	I
	Lawrence J. Kost	Community	OH	IV
EC Liaison	Gary A. Schnabel	Board Executive	OR	VII

Agenda Item F

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: September 4, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Implementation of Enforcement Provisions from SB 361 (Pending)**

SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Anticipating that the Governor will sign the legislation, the following compliance provisions will be added to California Pharmacy Law effective January 1, 2004.

- **Section 4083 – Order of Correction**
  Would allow an inspector to issue an order of correction to a licensee directing the licensee to comply with Pharmacy Law within 30 days by submitting a corrective action plan to the inspector, or the licensee can contest the order of correction to the executive officer for an office conference. If an office conference is not requested, compliance with the order does not constitute an admission of the violation noted in the order of correction and the order of correction is not considered a public record for purposes of disclosure. The licensee must maintain on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date the order was issued.

- **Add Section 4315 – Letter of Admonishment**
  Would authorize the executive officer to issue a letter of admonishment to a licensee for failure to comply with Pharmacy law and directing the licensee to come into compliance within 30 days by submitting a corrective action plan to the executive officer documenting compliance, or the licensee can contest the letter of admonishment to the executive office for an office conference. If an office conference is not requested, compliance with the letter of admonishment does not constitute an admission of the violation noted in the letter of admonishment. The licensee must maintain on the pharmacy premises a copy of the letter of admonishment and corrective action plan for at least three years from the date the

letter was issued. The letter of admonishment would be considered a public record for purposes of disclosure.

- **Add Section 4314 – Issuance of Citations**
  Would allow the board to issue an order of abatement that would require a person or entity to whom a citation has been issued to demonstrate how future compliance with the Pharmacy Law will be accomplished and provides that such demonstration may include, but not be limited to, submission of a corrective action plan, as well as requiring the completion of up to six hours of continuing education courses in subject matter specified in the order of abatement.

Agenda Item G

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 4, 2003

From: Paul Riches
Chief of Legislation and Regulation

Subject: Summary of Senate Bill 151

Senate Bill 151 (Burton) repeals the triplicate prescription requirement for Schedule II controlled substance prescriptions and substantially revises California law regarding the prescribing of controlled substances generally. This memo will outline the changes contained in this legislation. Generally, this bill repeals the triplicate and replaces it with a tamper resistant prescription form that may be obtained from approved printers. This new form will be required for all controlled substance prescriptions after a phase-in period. The bill also will require pharmacies to report Schedule III controlled substance prescriptions to the CURES system.

Because of the expansive nature of the changes required by SB 151, the new requirements are phased in over a 12 month period. Below is a calendar outlining when the most significant elements of the bill become effective.

January 1, 2004 –

- The Board of Pharmacy (board) and the Department of Justice (Department) may approve security printers to produce the new controlled substance prescription forms.
- Permit mail order pharmacies to apply the prescription requirements of the state in which the patient resides when filling prescriptions.
- Controlled substance prescriptions (Schedules II-V) are valid for six-months.
- Requires all pharmacies to report Schedule II controlled substance prescriptions to the Department in a time and manner of the Department's choosing.
- Requires that Schedule III-IV controlled substance prescriptions be signed and dated by the prescriber.
- Controlled substance prescription forms may be acquired from approved security printers.

- Requires controlled substance prescription forms to have the following features:

  (1) Latent "void" protection so that if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
  (2) Watermark with the text "California Security Prescription" printed on the back of the prescription.
  (3) Chemical void protection that prevents alteration by chemical washing.
  (4) Feature printed in thermo-chromic ink (the ink changes color when exposed to heat).
  (5) Feature using micro-printing (the text becomes a line if the prescription is copied or scanned).
  (6) Description of the security features included on each prescription form.
  (7) Quantity check off boxes printed on the form in the following quantities: 1-24, 25-49, 50-74, 75-100, 101-150, 151 and over.
  (8) Either of the following statements:
    (a) "Prescription is void if more than one controlled substance prescription is written per blank" or
    (b) Contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
  (9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.
  (10) A check box indicating the prescriber's order not to substitute.
  (11) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

July 1, 2004 –

- The Department may no longer produce or distribute triplicate prescription forms.

- Triplicate prescription forms may be used to prescribe Schedule II controlled substances.

- Prescribers may use the new controlled substance prescription forms for Schedule II controlled substance prescriptions.

- Oral and electronic orders for Schedule II controlled substance prescriptions for patients in skilled nursing facilities, intermediate care facilities, home health care programs, and hospice programs are permitted. Such orders must be reduced to hard copy form and signed by the pharmacist on a form of the pharmacy's design.

- Requires prescribers dispensing Schedule II controlled substances to report those prescriptions to the CURES system.

January 1, 2005 –

- Triplicate prescription forms are no longer valid.
- All written controlled substance prescriptions (oral and fax orders for Schedules III-V are still permitted) shall be on controlled substance prescription forms.
- Pharmacies must report Schedule III controlled substance prescription information to the CURES system.
- Prescribers dispensing Schedule III controlled substances must report those prescriptions to the CURES system.

The Licensing Committee is reviewing a draft process for approving security printers at its September 10, 2003 meeting.

Agenda Item H

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: September 8, 2003**

From: **Patty Harris**
Executive Officer
Board of Pharmacy

Subject: **Prescription Requirements for Dispensing Non-Dangerous Drugs/Devices for Medi-Cal Reimbursement**

At its last meeting, the Enforcement Committee discussed a complaint received from a pharmacist via the California Pharmacists Association regarding the dispensing of medical supplies. During the inspection of this pharmacist's pharmacy in 1992, the inspector advised the pharmacist that since medical supplies require a prescription (for purposes of reimbursement), then the pharmacy is subject to the requirements of Business and Professions Code sections 4040, 4051 and 4076. These sections specify the requirements of a prescription, that only a pharmacist can dispense prescription items and prescription labeling requirements.

Currently legislation is pending, SB 857 (Speier) that would add section 14170.10 to the Welfare and Institutions Code that clarifies the prescription requirement for non-prescription items in order for providers to be reimbursed by Medi-Cal. In addition, CCR, title 22, sec. 51320, authorizes the coverage of medical supplies when prescribed by a licensed practitioner. These two provisions are consistent with the inspector's direction provided to the pharmacist in 1992.

Representatives from Medi-Cal have been invited to attend the Enforcement Committee meeting to discuss the prescription requirements for Medi-Cal reimbursement.

-----Original Message-----
From: Lucy Michael [mailto:lmichael@wecarepharmacy.com]
Sent: Thursday, June 19, 2003 12:42 PM
To: Bill Bradley
Subject: legislative

Hello Bill,

I am dealing with an interesting situation with the Board of Pharmacy. We, at We Care Pharmacy, dispense large volumes of medical supplies including incontinence supplies, ostomy, entral feeding and nutritional supplements. Because Medi-Cal requires that these supplies be prescribed by a physician, the Board of Pharmacy has recently required us to label diapers and the like with a prescription label citing BPC 4076. It has also required that a pharmacist dispense these items citing BPC 4051. The hang up: as long as the orders written on a piece of paper that says "Prescription", then it must be treated like legend items.

We Care Pharmacy has been inexistence for close to 20 years and has been audited several times in the past. Only in the last audit (2002) that this requirement was made.

Other DME business can dispense the same products, written on a prescription, without labeling them and without having to have a pharmacist dispense them. They can even dispense legend devices without having to comply with these requirements. Not only that, but I understand now that the Board of Pharmacy no longer oversees DME businesses.

You can imagine the burden this has created and the competitive disadvantage this puts us in. Not to mention the waste of time, training, and skill of a full time pharmacist doing nothing but dispensing and labeling diapers, protective underwear, protective sheeting, etc. I spent a fair amount of time studying the pharmacy law to see where the law stands on that. My review of pharmacy revealed the following findings:

> The Pharmacy law deals with the practice of pharmacy as it relates to legend items, that is, dangerous drugs and devices or drugs and devices requiring a prescription issued by a licensed practitioner authorized by the law to issue such a prescription. Article 2 of the Business and Professions Code contains definitions governing the construction of the chapter and the use of terminology in the chapter **(PBC article 2 section 4015).**
> **BPC article 2 section 4022** clearly defines dangerous drugs and dangerous devices – the items for which the Board of pharmacy may have jurisdictions – as bearing the legend "Caution: federal law restricts this device to sale by or on the order of a ……." , "Rx only" or similar words.
> Diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies DO NOT bear such warning.

Diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies ARE NEITHER DRUGS NOR DEVICES.

The requirement of a prescription to dispense Diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies is imposed by insurance and government payers for payment purposes. The above items can be purchased from a grocery store or a drug store without a physicians order or a prescription. However, in order for the insurance to pay for it, a physician must authorize it. Prescription is a "word of art" unique to the medical field to indicate a 'doctor's order'. Physicians write 'prescriptions' for diet, exercise, rest, vacations, physical therapy, and other things that the pharmacist may have nothing to do with. Prescription is simply a "word of art" for the practice of medicine.

Based on the above, BPC section 4076 referenced by the inspector as the authority to order labeling of diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies DOES NOT APPLY.

BPC Article 1 section 4007explicitly states that the law does not authorize the board to "… adopt any rule or regulation that would require that a pharmacist personally perform any function for which the education, experience, training, and specialized knowledge of a pharmacist are not reasonably required." It does authorize the Board to pass rules if there are consumer safety issues. Obviously, if there are consumer safety issues with diapers and protective underwear, the Board would have passed some rules to deal with it.

Therefore, **BPC 4051** referenced by the inspector as grounds for requiring a pharmacist to dispense diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies is in direct conflict with **PBC article 1 section 4007**. Not only that the sale of diapers, protective underwear, pads, incontinent supplies, ostomy supplies, nutritional supplements, first aid, wound care products, and other home health care supplies is not governed by pharmacy law, but the board may not place unreasonable demands on pharmacists and business according PBC article 1 section 4007.

To have these items dispensed by a pharmacist and labeled with a prescription label is cost-prohibitive and would put us at a great competitive disadvantage, considering that Medical Device Retailers, who do not fall under the jurisdiction of the Board of Pharmacy, may operate a similar business without incurring the cost of hiring a full-time pharmacist to dispense and label diapers, canes, protective underwear, and the like. I trust that the intent of the Pharmacy Law is more reasonable than that, and would appreciate your insight and suggestions.

We have secured legal assistance to represent us in this matter. I am, however, interested in CPhA's position on this. I am also interested in knowing if CPhA has access to old Board minutes. Specifically, I am interested in Board minutes from 2000, the year the law changed and the Board of Pharmacy gave up licensing DME businesses.

Also, I would like to ask of CPhA can explore the issue with the Board of Pharmacy in the upcoming Board meeting.

I welcome interested in any insight of helpful thoughts you may offer.

Regard,

Lucy Michael, PharmD, MS

number of licensees of these boards, placed on probation during the immediately preceding calendar year, who are:

(1) Not receiving Medi-Cal reimbursement for certain surgical services or invasive procedures, including dental surgeries or invasive procedures, as a result of subdivision (a).

(2) Continuing to receive Medi-Cal reimbursement for certain surgical or invasive procedures, including dental surgeries or invasive procedures, as a result of a determination of compelling circumstances made in accordance with subdivision (a).

(c) This section shall become inoperative on July 1, 2005, and, as of January 1, 2006, is repealed, unless a later enacted statute that is enacted before January 1, 2006, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 16. Section 14170.10 is added to the Welfare and Institutions Code, to read:

14170.10. (a) No provider shall submit a claim to the department or its fiscal intermediaries for the dispensing or furnishing of a controlled drug, a dangerous drug, or a dangerous device, or a drug or device requiring a written order or prescription for the drug or device to be covered under the Medi-Cal program or for the performance of a clinical laboratory test or examination, unless the provider's records contain an order authorized by Section 4019 of the Business and Professions Code, or a prescription, including an electronic transmission prescription, signed by the person lawfully authorized by his or her practice act to prescribe or order the dispensing or furnishing of that drug or device to, or for the performance of a clinical laboratory test or examination that meets the federal CLIA standard for test requisition as set forth in Section 493.1241 of Title 42 of the Code of Federal Regulations upon, a Medi-Cal beneficiary, except the following:

(1) Providers who are physicians, clinics, hospitals, or other nonpharmacists and who are legally authorized to dispense or furnish drugs or devices directly to their patients, may in lieu of the requirements of this subdivision include a notation in their patients' medical charts reflecting they have dispensed or furnished the drug or device directly to the patient as authorized by the Business and Professions Code.

(2) Anatomical pathology examinations may be ordered by physicians by notation within the patients medical record during

inpatient or outpatient surgery provided that these examinations comply with federal CLIA requirements. Any claims made contrary to this section shall be subject to recovery as overpayments.

(3) If obtaining a biological specimen is required in order that a test or examination occurs on a periodic basis within an established provider-patient relationship *or the furnishing or dispensing of drugs or devices occurs on a periodic basis within an established provider-patient relationship,* the provider shall only be required to retain the order or requisition upon obtaining the biological specimen necessary for the initial test or examination *or initial furnishing or dispensing of the drug or device,* so long as an appropriate record of each test or examination*, or furnishing or dispensing,* is entered in the patient's chart.

(b) For purposes of this section:

(1) ''Signed'' shall include a signature that meets the conditions of the Electronic Signature in Global and National Commerce Act (15 U.S.C. Sec. 7001).

(2) ''Controlled substance'' shall mean any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code.

(3) ''Dangerous drug'' or ''dangerous device'' has the same meaning as in Section 4022 of the Business and Professions Code.

(4) ''Drug or device'' means:

(A) ''Drug,'' as defined in Section 4025 of the Business and Professions Code.

(B) ''Device,'' as defined in Section 4023 of the Business and Professions Code.

(C) Pharmaceuticals, medical equipment, medical supplies, orthotics and prosthetics appliances, and other product-like supplies or equipment.

(5) ''Prescription'' has the same meaning as in Section 4040 of the Business and Professions Code.

(6) ''Electronic transmission prescription'' includes both image and data prescriptions.

(7) ''Electronic image transmission prescription'' means any prescription order for which a facsimile of the order is received by a pharmacy or other appropriate provider from a licensed prescriber and that is reduced to writing and processed by the

pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070.

(8) ''Electronic data transmission prescription'' means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy or other appropriate provider and which is reduced to writing and processed by the pharmacy or other appropriate provider in accordance with applicable provisions of the Business and Professions Code, including Section 4070. The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(9) ''Clinical laboratory test or examination'' means the detection, identification, measurement, evaluation, correlation, monitoring, and reporting of any particular analyte, entity, or substance within a biological specimen for the purpose of obtaining scientific data that may be used as an aid to ascertain the presence, progress, and source of a disease or physiological condition in a human being, or used as an aid in the prevention, prognosis, monitoring, or treatment of a physiological or pathological condition in a human being, or for the performance of nondiagnostic tests for assessing the health of an individual.

(c) Notwithstanding any other provision of law, the director may, without taking regulatory action pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, implement, interpret, or make specific this section by means of a provider bulletin or similar instruction. The department shall notify and consult with interested parties and appropriate stakeholders in implementing, interpreting, or making specific the provisions of this section, including all of the following:

(1) Notifying provider representatives of the proposed action or change. The notice shall occur at least 10 business days prior to the meeting provided for in paragraph (2).

(2) Scheduling at least one meeting with interested parties and appropriate stakeholders to discuss the action or change.

(3) Allowing for written input regarding the action or change.

(4) Providing at least 30 days' advance notice on the effective date of the action or change.

California Code of Regulations
Title 22

§51320. Medical Supplies.

(a) Medical supplies are covered when prescribed by a licensed practitioner within the scope of his practice as defined by California laws, subject to the requirements in Section 59998.
(b) Common household items and articles of clothing are not covered.
(c) Medical supplies for chronic outpatient hemodialysis provided in renal dialysis centers and community hemodialysis units or for home dialysis are covered, but are payable only when included in the all inclusive facility rate set forth in Section 51509.2.

NOTE

Authority cited: Sections 14105 and 14124.5, Welfare and Institutions Code. Reference: Sections 14105, 14124.5, 14132, and 14133, Welfare and Institutions Code.

HISTORY

1. Amendment of subsection (a) filed 5-14-76 as an emergency; effective upon filing (Register 76, No. 20). For prior history, see Register 73, No. 5.
2. Certificate of Compliance filed 9-8-76 (Register 76, No. 37).
3. Amendment filed 4-24-81; designated effective 7-1-81 (Register 81, No. 17).

Agenda Item I

California Medical Association
Physicians dedicated to the health of Californians

August 25, 2003

Ron Joseph
Executive Director
Medical Board of California
1426 Howe Avenue, Suite 54
Sacramento, CA 95825

Patricia Harris
Executive Officer
California Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Re: Internet Pharmacies

Dear Mr. Joseph and Ms. Harris,

On behalf of California Medical Association's Subcommittee on the Physicians' Confidential Line, I wish to applaud the Medical Board of California (MBC) and California Board of Pharmacy in its continued efforts in monitoring the illegal prescription of drugs via Internet pharmacies, reflected in a number of actions by both Boards against physicians and pharmacists for improper prescribing and dispensing.

As anyone with on-line capabilities will attest, on a daily basis we are bombarded with ads proclaiming "Viagra, Merida, Prozac, Paxil, Phentermine, No examination required." The existence of online distribution of prescription medications and controlled substances is a reality.

Sometime in May 2003 that fact was well demonstrated to me when I admitted a patient to a chemical dependency unit for treatment of Vicodin, Valium and Soma abuse. For months the patient had been obtaining her drugs without seeing a physician. This patient merely logged on to any one of the online pharmacies, filled out a questionnaire, gave a credit card number, and then awaited the delivery of the drugs.

Every quarter all California-licensed physicians receive MBC's Action Report. Part of this publication is devoted to reporting physicians being disciplined for violations of the Medical Practice Act. Oftentimes the offense is prescribing controlled substances without a good-faith medical examination. Online pharmacies attempt to circumvent this law with the use of questionnaires and a "consultation" with their in-house physician who "approves" the prescription. Perhaps it would be useful to remind physicians in Action Report article about their obligations with respect to good faith examinations and Internet prescribing.

I have attempted to e-mail a number of Internet pharmacies to inquire how they "get around" the law requiring a good faith exam. As I expected, I have not received a reply. We continue to support you in your crusade against these "rogue" sites. Given the international scope and technical nature of this issue, our efforts to combat this problem could have far-reaching impact, and not only for California consumers.

Thank you for your good work. Please let us know if there is something we can do to assist.

Sincerely,

Leland G. Whitson, M.D.
Past Chair, CMA's Committee on Well-being of Physicians and
Subcommittee on the Physicians' & Dentists' Confidential Line

cc: Members of the Committee on Well-being of Physicians
Members of the Physicians' Confidential Line
Sandra E. Bressler
Margaret Chow

Agenda Item J

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Of Counsel: ALLEN D. EMMEL*

September 3, 2003

Enforcement Committee
c/o Patricia Harris, Executive Officer
California State Board of Pharmacy
400 R. Street, Suite 4070
Sacramento CA 95814

Re: Compounding Issues: Labels and Central Fill

Dear Enforcement Committee:

On behalf of several clients and the Compounding Pharmacists Section of the California Pharmacists Association, thank you for putting these issues on the agenda for the next Enforcement Committee Meeting.

1. Labels on Compounded Products.
An issue that has been brought to the attention of several compounding pharmacists involves the *appropriate content* of labels of compounded products. There is widespread agreement with the Board that current label requirements reflect information that is needed by consumers when they receive compounded products. The problem arises when the compounded product is provided in multiple units of a dosage form – i.e. suppositories, single dose vials, etc. – for which individual product labels are either not feasible, cost prohibitive or even a hindrance to treatment. For instance, many creams are dispensed in application syringes that contain multiple doses of the product. Graduations on the syringes are used to measure the individual dose. Because of their size, placing a label on each syringe would obstruct these graduations, making accurate dosing difficult or impossible.

The question raised is: What, if any, information does the Board feel should be included on individual units of compounded products that are dispensed to patients?

In the opinion of the pharmacists we surveyed, this should be a matter for the individual discretion of the compounding pharmacist. In many cases, individual doses should contain some sort of label to indicate the active ingredients. The form of this label will vary depending on the dispensing unit and available space. In other cases, a label on individual doses will result in little *or no benefit and will cause more problems than it solves. In the case of compounded tablets and* capsules, identification of any kind on individual doses simply isn't practical.

In any case, the patient should be made aware of the situation and advised to always keep the doses in the box, bag or container in which it was dispensed and which is labeled with the information that may be needed by a family member or emergency personnel in the event of a problem.

To clarify existing law and resolve any conflicts that may arise, we ask that the Board of Pharmacy weigh in on this issue. We welcome the opportunity to participate in a dialog to reach a reasonable and agreeable guideline for labels on compounded products.

2. Compounding in Central Fill Pharmacies

Many pharmacists and pharmacies are specializing in compounded products. The value of these products is broadly recognized. The Board's recent activities with regard to compounding of sterile injectable products has provided needed focus on the systems and facilities needed for the safe compounding of sterile injectables.

For a large number of compounded products, similar, if less stringent, systems and facilities are needed for the preparation of products to assure consistency in preparation and potency. Pharmacies that specialize in this practice have invested in those systems and facilities and, as evidenced by the growth in this area of practice, the products they compound are accepted as effective and safe.

We believe consumers should have improved access to compounded products. A safe and cost-effective way to accomplish this is to allow compounding pharmacies to act as central fill pharmacies for compounded products in the same way as is allowed for other prescriptions under CCR 1707.4. The Board has authorized similar activity for parenteral products for many years (cf B&P sec. 4123). We believe allowing central filling of compounded products under the provisions of 1707.4 will improve access for consumers, reduce costs and result in the provision of more consistent, safer and more effective compounded products.

We ask the Board to move forward on this proposal and are willing to work with the Board to resolve any problems that stand in the way of this application of section 1707.4.

I look forward to discussing these proposals further at the upcoming Enforcement Committee meeting.

Sincerely,

John Cronin

John Cronin, Pharm.D., J.D.